

WILMERHALE

Via ECF & Federal Express

Robert J. Gunther, Jr.

February 28, 2012

+1 212 230 8830(t)

+1 212 230 8888(f)

robert.gunther@wilmerhale.com

The Honorable F. Dennis Saylor, IV
United States District Judge
United States District Court
Donohue Federal Building
595 Main Street
Worcester, MA 01608

Re: *Abbott GmbH & Co., KG et al. v. Centocor Ortho Biotech, Inc., et al.*, C.A. No. 4:09-cv-11340; *Centocor Ortho Biotech, Inc., v. Abbott GmbH & Co., KG*, C.A. No. 4:10-cv-40003

Dear Judge Saylor:

This letter is submitted on behalf of Abbott in order to advise the court of *Dow Chemical Co. v. Nova Chemicals Corp. et al.*, No. 2010-1526 (Fed. Cir. Jan. 24, 2012) (“*Dow Chemical*”, “*Dow*”), a recent decision from the United States Court of Appeals for the Federal Circuit, a copy of which is attached as Exhibit A.

In *Dow Chemical*, the Federal Circuit resolved an appeal relating to, among other things, an assertion by the accused infringer, Nova, that the asserted claims were indefinite and therefore invalid.¹ The Federal Circuit’s holding that the claims were not indefinite in view of the asserted patent’s specification and the knowledge of one of skill in the art is relevant to the pending motions for summary judgment filed by Abbott and Centocor relating to Centocor’s indefiniteness defense in this case.²

In *Dow Chemical*, the asserted claims referred to polymer compositions which were required to meet a test such that the compositions have a specific slope strain hardening coefficient (“SLC coefficient”). Slip op. at 15-16. The asserted claims provided no specific guidance as to how the SLC coefficient, which was a new concept developed by Dow and not previously known in the art, should be determined. The Federal Circuit rejected each of Nova’s arguments relating to indefiniteness:

- Nova pointed out that the text of the patent referred to a figure that would instruct persons of ordinary skill how to measure for the SLC coefficient, but the figure was inexplicably missing from the patent specification. The Court rejected this argument, holding that one of ordinary skill in the art would nevertheless have known at the time how to determine the information which should have been included in the figure. *Id.* at 17-19. The same

¹ Although the Federal Circuit designated the Dow Chemical decision as “non-precedential,” the Court is entitled to consider this decision in its determination of the indefiniteness defense raised in this case. *See* Fed. Cir. R. 32.1(c) and 32.1(d).

² The relevant motions are Abbott’s Motion for Summary Judgment No. 3 and Centocor’s Motion for Summary Judgment No. 1.

WILMERHALE

February 28, 2012

Page 2

result should apply in this case, where the claim terms that Centocor has challenged, including “surface plasmon resonance,” “Kd,” and Koff” were not only terms that were understood by those skilled in the art long before the asserted ‘128 and ‘485 patents were filed, but also the common specification of the asserted patents provided definitions for each of these terms.

- Nova also argued that the claims were indefinite because internal Dow documents showed that Dow had experimented with four different methods to determine the SLC coefficient, none of which were disclosed in the patent specification. The Court rejected this argument, noting that claims are not indefinite even if some experimentation is required to determine the exact scope of the claims, and concluded that “the mere fact that the slope may be measured in more than one way does not make the claims of the patent invalid.” *Id.* at 19-20. Consistent with this reasoning, as set forth in Abbott’s briefing on the motions for summary judgment, a person of ordinary skill in the art at the time of the invention of the claimed IL-12 antibodies would understand that routine experimentation would be performed to determine the appropriate testing conditions to reliably and accurately determine the Kd for the particular IL-12 antibody / antigen interaction being tested.
- Finally, Nova argued that the fact that the patent failed to specify any particular unit of measurement for the SLC coefficient rendered the asserted claims indefinite. *Id.* at 16-22. In rejecting this argument, the Court looked to the fact that the patents described a particular machine (an Instron Tensile Tester) and that the user manual for this machine, available when the patents-in-suit were filed, specified English units of measurement. *Id.* at 20-22. Here, the asserted patents similarly identify a specific machine used to perform the surface plasmon resonance measurements, the BIACore system; the common specification details the performance of experiments using this machine, and persons of ordinary skill in the art would rely on the teachings in the literature, including the BIACore manuals, in performing this testing.

WILMERHALE

February 28, 2012

Page 3

For these reasons, Abbott submits that the *Dow Chemical* decision provides further support for the conclusion that the asserted claims of the '128 and '485 patents are definite as a matter of law.

Respectfully yours,

/s/ Robert J. Gunther, Jr./

Robert J. Gunther, Jr.

Enclosures

cc: Dianne B. Elderkin (via email)
Barbara L. Mullin (via email)